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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,388	11/21/2001	Wataru Morikawa	MORIKAWA4A	1349

7590 10/20/2004

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,388

Applicant(s)

MORIKAWA ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments and Amendments

1. Claims 1-4 are pending.

Claim 1 has been amended.

Claims 1-4 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

3. The information disclosure statement filed July 15, 2003 continues not be considered in its entirety. There are several references that did not accompany the file. These references are AD, AH, AK, AM, and AO and the information referred to therein has not been considered as to the merits and have been "lined through". The listings have been lined through and Applicants are invited to resubmit these documents. The Examiner has previously requested information regarding this matter. It is requested that Applicants respond accordingly.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

4. The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

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5. The rejection of claim 1 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for inhibiting lung tumor metastasis and lung tumor growth, does not reasonably provide enablement for a composition for inhibiting any and all tumor metastasis and any and all tumor growth is withdrawn in light of the claim amendment.

6. The rejection of claims 1-4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the claim amendment.

Claim Rejections - 35 USC § 102

7. The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent number 5,288,489 (February 22, 1994/ IDS reference AA is withdrawn in light of Applicants' arguments.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

8. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicants have amended claim 1, section c to read "under physiologic ionic conditions". Applicants have not pointedly expressed where in the specification support for this recitation is found. Applicants are requested to list the page and line number in the specification where new language is evidenced or delete the new matter.

9. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for inhibiting lung tumor metastasis and lung tumor growth, does not reasonably provide enablement for a composition for inhibiting any and all tumor metastasis and any and all tumor growth. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants have set forth data that supports the inhibition of lung cancer metastasis and growth, as well as the inhibitory effects of fractions with heparin binding activity on lung tumor metastasis and growth, see Examples 7, 8 and 9, pages 21-23 corresponding to Figure 7 and 8; Example 10, page 24 corresponding to Figure 9.

However, the breadth of the claims encompasses the broad treatment of tumor metastasis and tumor growth and the specification is insufficient to enable one of skill in the art to practice the invention absent an undue amount of experimentation. Some of the considerations in determining what constitutes undue experimentation have been summarized as follows: (1) the amount of direction or guidance presented; (2) the presence or absence of working examples; (3) the breadth of the claims; (4) the state of

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the prior art; (5) the predictability or unpredictability of the art. *Ex parte Formal, et al.*, 230 USPQ 546 (BPAI, 1986).

As set forth in IDS document, AG the potential for using agents, such as cytokines and antibodies in cancer therapy is great, but clinical results to date have not met the high expectation extrapolated from carefully planned and performed preclinical studies, see bridging paragraph of pages 1079 and 1080. Well-established cancer agents must overcome the physiological barriers to penetrate tumor tissue, effective in *in vivo* microenvironment of solid tumors and reach the target cells *in vivo* in effective quantities with minimal toxicity to normal tissues, see first full paragraph of column 1, page 1080. Applicants claimed cancer agents has not established a sufficient precedent in treatment of a variety of tumors. Applicants have provided data that supports the administration of an effective dose of Lys-LBS-I to immunodeficient mice, however one cannot extrapolate the results based upon one type of tumor to all tumor types.

The selection and development of such therapeutics is art known to be highly unpredictable. The specification exemplifies no examples of the effective use of any composition consisting of Kringles 1 to Kringle 3 of a naturally occurring plasminogen other than the human Lys-LBS I fragment of human plasminogen as a therapeutic pharmacological agent. Therefore, due to the unpredictability of therapeutics and the absence of any evidence concerning the effectiveness of the broadly claimed composition as a pharmacological agent, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and use with a reasonable expectation of success, the invention commensurate in scope with this claim.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1 is indefinite in the recitation "preparing Lys-plasminogen from human plasminogen either by adding plasminogen to a solution...". Applicants are requested to review the claim language and clarify.

Maintained Rejection

Claim Rejections - 35 USC § 102

12. The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent number 5,288,489 (February 22, 1994/ IDS reference AA) is maintained.

Applicants have submitted two declarations authored by inventor, Wataru Morikawa in order to obviate the instant rejection. Applicants argue that the fragment of the patent/ Reich is not able to inhibit lung tumor metastasis and lung growth and does have activity to inhibit growth of endothelial cells of blood vessels, see page 8, first full paragraph of Remarks submitted August 4, 2004. Applicants also aver that the present invention is directed to inhibition of lung tumor growth and metastasis and the target

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disease state or condition is quite different from those of Reich, see page 13, second full paragraph of Remarks. The declarations and these points of have been carefully considered, but found unpersuasive.

It is clear that the product by process claimed is the same as the product by process claimed. Inherently, this disclosed product made by the disclosed process would inhibit lung tumor metastasis and lung tumor growth, as well as have the molecular weight claimed, lack of glycosylation and heparin binding activity, qualities of the recovered compound (which encompasses the Lys-Lysine binding site I. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Furthermore, absent evidence to the contrary the product of process disclosed in the patent is the same as that claimed.

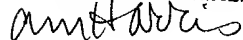
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between hours of 6:30 am to 5:30 pm with alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER



Alana M. Harris, Ph.D.
18 October 2004